STATE OF MICHIGAN

IN THE SUPREME COURT

TAMARA TAYLOR, LEE ANNE RINTZ,

Plaintiffs-Appellees,

v.

Case Nos. 120642-120645

GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, MEDEVA PHARMACEUTICALS, INC. and AMERICAN HOME PRODUCTS CORPORATION, et al,

COA Nos. 217328, 217269, 216279, 217290 (Consolidated)

Defendants-Appellants,

and

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v.

Case No. 120646

GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, MEDEVA PHARMACEUTICALS, INC. and AMERICAN HOME PRODUCTS CORPORATION, et al,

COA No. 227700

Defendants-Appellants.

_____/

PLAINTIFFS-APPELLEES' COMBINED BRIEF ON APPEAL

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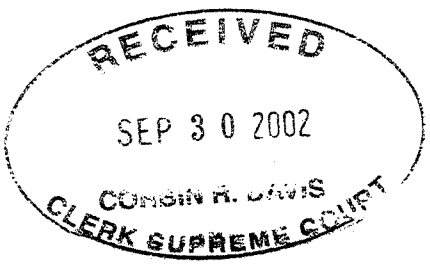

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STATE OF MICHIGAN

IN THE SUPREME COURT

TAMARA TAYLOR, LEE ANNE RINTZ,

Plaintiffs-Appellees,

v.

Case Nos. 120624, 120637-40, 120642-6

GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, MEDEVA PHARMACEUTICALS, INC., AMERICAN HOME PRODUCTS CORPORATION, A.H. ROBINS, COMPANY, INCORPORATED and WYETH-AYERST LABORATORIES COMPANY,

COA Nos. 217328, 217269, 216279, 217290

LC No. 97-731636-NP

Defendants-Appellants,

and

ZENITH GOLDLINE PHARMACEUTICALS, INC. ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICAL COMPANY, INC., ION LABORATORIES, INC., INTERNEURON PHARMACEUTICALS, INC., CAMALL COMPANY, LABORATORIES SERVIER and ALL MICHIGAN PHYSICIANS WHO PRESCRIBED OR GAVE FEN-PHEN AND/OR REDUX TO MICHIGAN PATIENTS,

Defendants,

and

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v.

Case Nos. 120641, 120646 120654

GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, MEDEVA PHARMACEUTICALS, INC., AMERICAN HOME PRODUCTS CORPORATION, A.H. ROBINS, COMPANY, INCORPORATED and WYETH-AYERST LABORATORIES COMPANY,

COA No. 227700

LC No. 97-731636-NP

Defendants-Appellants,

and

JOYCE KAFERLE, M.D., EVELYN ECCLES, M.D., ZENITH GOLDLINE PHARMACEUTICALS, INC. ABANA PHARMACEUTICALS, INC., RICHWOOD

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PLAINTIFFS-APPELLEES' COMBINED BRIEF ON APPEAL

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RESPONSE TO DEFENDANTS' STATEMENTS IDENTIFYING THE JUDGMENTS APPEALED FROM AND RELIEF SOUGHT

Plaintiffs-Appellees agree with Defendants' statements identifying the judgment appealed from and relief sought.

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STATEMENT OF QUESTIONS PRESENTED

I. **DID THE COURT OF APPEALS CORRECTLY DETERMINE THAT MCL 600.2946(5) IS UNCONSTITUTIONAL, IN THAT IT IMPROPERLY DELEGATES TO A FEDERAL EXECUTIVE AGENCY THE LEGISLATIVE POWER OF DETERMINING WHETHER A PARTICULAR DRUG MAY FORM THE BASIS OF A PRODUCT LIABILITY ACTION IN MICHIGAN?**

Plaintiffs-Appellees answer "Yes."

Defendants-Appellants argue "No."

The Wayne County Circuit Court answered "Yes."

The Washtenaw County Circuit Court answered "No."

The Court of Appeals answered "Yes."

INTRODUCTION

This consolidated appeal involves the constitutionality of MCLA 600.2946(5), the so-called "drug manufacturer immunity" provisions of the "tort reform" acts of 1996.

Whether or not this act, and its provisions, are wise or unwise, is not the issue. Instead, the issue is whether the legislature chose a constitutional means of accomplishing its end. Because the legislature delegated to the FDA the decision of what drugs may legally be the subject of a court action in Michigan, and because the legislature accomplished this without incorporating the entire process by which the FDA accomplishes its own ends, the legislature chose an unconstitutional means violative of the separation of powers doctrine. For this reason, Plaintiffs will ask this Court to make a very rare decision—to hold a duly enacted statute unconstitutional.

Litigation History

In the Wayne County action, on April 17, 1998, one of the Defendants filed a motion for summary disposition based on the currently existing statutory bar. Plaintiffs responded, on May 29, 1998, attacking the constitutionality of MCLA 600.2946(5) on various grounds, i.e., (1) improper delegation of power to a federal agency; (2) violation of the open court's provision of the Michigan Constitution; (3) violation of the due process clause; and (4) violation of equal protection clause of the Michigan Constitution.

Oral argument was had on September 11, 1998. On November 24, 1998, the Wayne County Circuit Court issued its opinion in which it denied Defendant's motion for summary disposition on the grounds of unconstitutional delegation to a federal agency executive branch (FDA) of the state legislative function of determining what is a cause of action. However, the trial

court rejected Plaintiffs' constitutional challenges on the other grounds listed above. An order formalizing this opinion was entered on January 8, 1999.

Four Defendants filed application for leave to appeal to the Court of Appeals. By order dated May 24, 1999, this Court granted the applications of the four Defendant drug manufacturers, and consolidated the action into one consolidated appeal. On June 15, 1999, these Plaintiffs filed a cross-appeal.

The Robards action was filed as an individual action in the Washtenaw County Circuit Court. On April 12, 2000, the Washtenaw County Circuit Court, after hearing essentially the same arguments as occurred in the Taylor case before the Wayne County Circuit Court, granted Defendants' motion for summary disposition and dismissed the action. Plaintiffs appealed from this action, by right, to the Michigan Court of Appeals. On September 15, 2000, the Court of Appeals granted leave to appeal in Robards, and at the same time, consolidated Robards with the already existing case in Taylor.

Briefing was had, oral argument was held on September 5, 2001, and on November 30, 2001, the Court of Appeals issued its opinion upholding the Wayne County Circuit Court's denial of summary disposition, and reversing the Robards court's granting of summary disposition, on the basis that MCLA 600.2946(5) was unconstitutional as an improper delegation of legislative authority to a federal executive branch.

On August 28, 2000, United States District Court Judge Bechtle, of the Eastern District of Pennsylvania, entered Pretrial Order 1415, certifying and approving a nationwide settlement class in Redux and Fen-Phen cases. Brown v American Home Products Corp, 2000 WL 1222042 (ED Pa, 2000). This class settlement covers all Americans, in all fifty states—or 49, if this Honorable Court were to reverse the trial and appellate decisions, and allow Michigan plaintiffs to go

unprotected by tort law in cases involving defective drugs which were approved, but then withdrawn from the market, by the FDA.

MICHIGAN'S 1996 AMENDMENTS TO THE PRODUCT LIABILITY STATUTE

Legislative History

In 1995, becoming effective March 28, 1996, the Michigan legislature enacted 1995 PA 249, which rewrote MCL 600.2946. The act also added 600.2946a, which capped non-economic damages in product liability cases, including drug product liability. It rewrote §§ 600.2945, 600.2947, 600.2948, repealed 600.2949, added §§ 600.2949a, 600.2955, 600.2955a, 600.2956, 600.2957, 600.2958 and 600.2959. There is every evidence that the Michigan legislature intended these bills to be a comprehensive, unified new "system" of product liability law in Michigan.

The Product Liability Statute amendments had their origin in SB 344 and HB 4508. The SFA bill analysis from the Senate Fiscal Agency set forth the following reasons for the entire package of tort reforms that became PA 249 and PA 161 of 1995.

> The term 'products liability' refers to the body of law that governs the liability of manufacturers and sellers of products that are alleged to have caused personal injury or property damage. According to many, over the past several decades there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers, bankruptcies, reduced capacity of firms to compete internationally, curtailed innovation, reduced funding for research, higher consumers cost, and unaffordable or unavailable casualty insurance. These circumstances have led to considerable debate at both the federal and state levels, which escalated in the mid-1980s and continues in the present. This debate has been fueled, in part, by various highly publicized cases, including those involving flammable baby pajamas, asbestos, the Dalkon Shield, exploding gas tanks, and silicone gel breast implants. In Congress and state legislatures, a number of proposals have been advanced to reduce manufacturers' and sellers' exposure to liability.

> Among the most common recommendations are those that would establish a defense if a product met government standards; if a product were misused or modified by the consumer; if the harm were caused by an inherent characteristic of a product (one that cannot be removed if the product is to serve its function); or if the consumer exposed himself or herself to a known risk. Many also believe that a wholesaler or retailer should not be held liable unless the seller's negligence caused the injury; that the amount awarded for non-economic damages (e.g., pain and suffering) should be limited; and that a product liability defendant should not have to pay more than its share of the total damages.
>
> (Appendix at 7b, SFA bill analysis, SB 344 and HB 4508).

This manufacturers' "wish list" became Senate Bill 344, which became Public Act 249 of 1995. Specifically, the Senate analysis tracks the wish list, as a unified modification of Michigan's product liability system:

> Senate Bill 344 amends the Revised Judicature Act to do the following in regard to product liability actions;
>
> -- Provide that a manufacturer or seller is not liable if a practical and technically feasible alternative production practice was not available.
>
> -- Create a rebuttable presumption that a manufacturer or seller is not liable if the aspect of production that allegedly caused the injury complied with federal or state standards or was approved by a federal or state agency.
>
> -- Allow the admission in evidence, for certain purposes, of subsequent changes in theory, knowledge, technique, or procedure.
>
> -- Provide that a manufacturer or seller is not liable if the harm was caused by alteration or misuse of the product that was not reasonably foreseeable; if the user was aware of, and voluntarily exposed himself or herself to an unreasonable risk; or if the alleged harm was caused by an inherent characteristic of the product.
>
> -- Specify that a manufacturer or seller is not liable for failure to warn if the product was provided for use by a sophisticated user.
>
> -- Specify that a defendant is not liable for failure to warn of risks that should have been obvious to a reasonably prudent product user or that are a matter of common knowledge.
>
> -- Provide that a manufacturer or seller is not liable for a drug that was approved by the Food & Drug Administration.

-- Remove certain defenses for a defendant who had actual knowledge of a product's defect.

-- Limit damages for non-economic loss.

-- Redefine 'product liability action' to include injuries or death resulting from the sale of a product." (Id at 2).

Of particular importance to this litigation is subsection (5) as follows:

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States Food & Drug Administration, and the drug and its labeling were in compliance with the United States Food & Drug Administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States Food & Drug Administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States Food & Drug Administration information concerning the drug that is required to be submitted under the Federal Food, Drug, & Cosmetic Act, Chapter 675, 52 Stat 1040, 21 USC 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States Food & Drug Administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States Food & Drug Administration for the purpose of securing or maintaining approval of the drug.

(Emphasis provided.) (Appendix at 2b).

The "actual fraud" exception, which purports to balance the draconian effect of granting total immunity to drug manufacturers who sell their products in Michigan, is entirely meaningless. Specifically, the provision that plaintiff must show that the drug would not have been

approved or that the FDA would have withdrawn approval if adverse information had been timely submitted to the FDA, is impossible to prove. First, no FDA official has ever been allowed to be deposed on such a point. Therefore, there can never be competent testimony available for a plaintiff to show that the drug would not have been approved if the accurate information had been provided to the FDA. Second, no FDA official is empowered to make such a statement on his own behalf, or on behalf of the FDA. No one man or woman can say that an FDA committee would have denied approval of a particular drug "if. . .".

More importantly, the United States Supreme Court, in Buckman Co v Plaintiffs Legal Committee, 531 US 341; 121 S Ct 1012 (2001), held that any state law claim of "fraud on the FDA" is impliedly preempted by the Food, Drug & Cosmetic Act, 52 Stat 1040, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat 539, 21 USC § 301 (1994 Ed & Supp IV). The Buckman Co decision, as it applies to § 2946(5) would convert an immunity with an exception (which Plaintiffs have already pointed out above is illusory) to an absolute immunity, predicated upon a decision of a federal agency, even after that federal agency, as an inherent part of its functioning, has reversed that decision. For the reasons set out by the Court of Appeals, such is an unconstitutional delegation of authority from the state legislature to a federal agency.

The FDA is a federal agency, in the executive branch of government, funded by the federal government. As such, it is fully subject to the economic forces that are shaping the current downsizing/streamlining/reduction of federal budgets. Even those governed by the FDA are apprehensive about the cutbacks in enforcement. See, e.g., "CTFA's Kavanaugh Down on FDA Revamping," 1998 Capital Cities Media Inc., Feb 27, 1998 (Appendix at 28b).[1] The president of the

[1]Defendants below objected to Plaintiffs submitting outside materials, which was done to give the trial court a more complete view of the FDA process and the controversy swirling around it. The trial court specifically noted that it was overruling Defendants' objections, and considering the material placed before it by Plaintiffs in its opinion of November 24, 1998. As such, the material is properly submitted to this Court, and is part of the records before this Court regarding the constitutional issues presented herein.

Cosmetics, Toiletry & Fragrance Association states that "we'd like to see more funding at FDA for a lot of reasons, like credibility; a lot of other countries look to FDA, and we need a level playing field out there. . . . It sounds strange for an industry to be saying this, but we need a good cop on the corner. There is no question about it. . . and if we don't have that, we don't have a level playing field. The good companies are going to continue doing what they do, but it's going to become an invitation for sloppy operations. We can't have that."

Finally, an inherent part of the FDA process is receiving continuing feedback on an approved drug during the early stages of its public usage, then acting upon that feedback if it is excessively negative. Clearly, given the political currents, the FDA could be strengthened, weakened or totally eviscerated—without any change in the effect of the Michigan law granting immunity to drugs approved by the FDA. Further, the FDA does none of its own testing of drug safety and efficacy. Instead, the FDA relies on manufacturer performed and funded clinical studies. For these reasons, an initial FDA approval, without the inherent after-market review protection stage, cannot be counted on to protect Michigan citizens. Michigan is also the only state in the union that grants legislative immunity to prescription drug manufacturers.

History of the Drugs Involved in this Appeal

This litigation involves a combination of two drugs, Fen-Phen, and a drug, Redux, which is a close chemical cousin of one of the two components of Fen-Phen, Fenfluramine.

Fenfluramine, the Fen in Fen-Phen, has been on the market since 1973. Dexfenfluramine, Redux, has been sold in Europe since 1984, but was not introduced into the United States until 1996. (See Appendix at 33b and 36b, Physicians Desk Reference entries for Fenfluramine and Dexfenfluramine).

The FDA's approval process of Dexfenfluramine formally began on May 21, 1993. At that time, defendant Interneuron formally submitted its new drug application for Redux. After this was received, on December 15, 1993, the FDA received a letter from a group of neuro scientists sounding a safety alarm as to Redux, claiming studies showed brain disease in animals and might do the same things in humans. The scientists suggested further human studies be done before approval of the drug. Another memo, namely, a December 30, 1993 memo from Dr. Leo Lutwak to the file focused on the efficacy and toxicity of Redux. Kerr, "Doubts About Redux/Diet Drug OK'd Despite Qualms of FDA Officials," Newsday, Dec 17, 1997 at A07 (Appendix at 39b).

During the time that Dexfenfluramine (Redux) was being reviewed by the FDA, an Interneuron vice president (Redux's manufacturer) continuously called FDA officials for status reports. FDA officials documented these phone conversations, including conversations where Interneuron admitted it was so concerned with incoming primary pulmonary hypertension reports it considered withdrawing its application for FDA new drug approval. However, Interneuron backtracked, saying that it couldn't withdraw its application, because such a step would mean financial ruin for the company. (Id).

On September 28, 1995, an FDA advisory committee heard testimony on the pros and cons of Redux. At the end of the day, committee members approved the drug's efficacy, but suggested that further study of neurotoxicity and safety concerns merited a 5-3 decision against recommendation of approval of Redux. A second vote, however, was scheduled for November 15, and at the second meeting, the committee recommended approval by a 6-5 vote. Eventually, on April 29, 1996, the FDA accepted the advisory committee's report and approved Redux. (Id).

By the end of 1996, concerns about emerging heart valve failures and other cardiology problems began to be investigated by a number of doctors, including those at the Mayo Clinic. On July 8, 1997, doctors at Mayo Clinic informed the FDA that an apparent link had been established

between Fen-Phen and heart valve disease in women (Appendix at 44b). The FDA sounded an official alarm, and on September 15, 1997, the FDA announced the withdrawal of Fenfluramine and Dexfenfluramine (Appendix at 46b). One of the reasons for the September withdrawal is that, between July and September, the FDA received 66 additional reports of heart valve disease associated with Fen-Phen. There were also reports of cases where patients had taken only Dexfenfluramine (Redux), and also developed heart valve defects. (Id). The New England Journal of Medicine published two articles in its August 28, 1997 issue, reporting the dangers of use of these drugs (Appendix at 48b and 56b).

Between 1974 and 1997, 70 adverse reaction reports detailing deaths in patients who took Fen-Phen were submitted to the FDA. Furthermore, 545 adverse reaction reports were received by the FDA relating heart valve damage in patients taking Redux. Kerr, "Fen-Phen Reports Unheeded/FDA Didn't See Link," Newsday, Dec 22, 1997 at A06; Kerr, "Fen-Phen and Deaths: A Missed Link," Newsday, Oct 19, 1997 at A05 (Appendix at 66b). *These reports were not reviewed by FDA, the federal executive agency to which the Michigan legislature delegated the safety of Michigan citizens*. The FDA made no attempt to try to establish a link between the drugs and a possible side effect of heart conditions. Indeed, in 1997, the FDA said it had no way of checking whether the use of the diet drugs might have caused side effects associated with heart valve disease (Id).

The FDA, upon learning of the connection, issued a press release that the Mayo Clinic was publishing a study showing that fatal primary pulmonary hypertension and heart valve disease were linked to patients using Fen-Phen or Redux (Appendix at 44b). In fact, 24 cases of rare valvular disease were found in women who took the Fen-Phen combination therapy. The FDA immediately warned doctors that it had received nine additional reports of the same type, and requested that all health care professionals report any like cases to the agency or to the respective pharmaceutical manufacturers. Finally, on Sept. 15, 1997, the FDA asked the manufacturers to voluntarily withdraw

the drugs (Appendix at 46b). The manufacturers did so and, since that time, followup studies have indicated that there are a number of life-threatening problems associated with these two drugs, some known prior to FDA approval and some discovered after FDA approval. United States citizens from 50 states can sue for their injuries, unless this Honorable Court reverses Judge Battani and now the Michigan Court of Appeals. Then, on such a reversal, Michigan citizens, alone in the United States, would be without a remedy.

Overview of the FDA Process

A. Introduction

Informed commentators, inside and outside of the FDA, regularly point out that the FDA is underfunded and not up to the job of determining safety of drugs released into the American marketplace. At the beginning of the new drug approval process, there is no or inadequate monitoring of manufacturer studies. The FDA relies on drug manufacturers themselves to conduct the research upon which the FDA relies in approving a new drug. When a new drug application is before the FDA, there are significant pressures, from the manufacturers on one hand, and sufferers of medical conditions on the other, to quickly rubber stamp and shortcut the approval process. After a drug is approved, there is virtually no structured surveillance. The voluntary "reporting" system relies on overworked doctors to recognize a drug adverse effect. Then, that busy doctor, who may also not want to get involved in any followup investigation, has to figure out how and who at the FDA to inform, on a voluntary basis.

B. The Law Governing The Process

The FDA drug approval process involves a number of steps. First, the applicant must generate pre-marketing safety and efficacy information through human clinical trials. The approval process starts with an applicant's submission of an investigational new drug application (NDA) asking permission to conduct such trials. The application must also contain information about the chemical makeup of the drug, its pharmacology, any toxicology, and must include the results of animal and laboratory testing. 21 CFR 312. The FDA can approve, or simply fail to respond, and the trials may commence; the FDA may also request more information or may seek modification of the protocols for proposed clinical trials. Kessler, "The Regulation of Investigational Drugs," 320 New Eng J Med 281 (1989) (Appendix at 74b).

The "clinical trials" involve tests done with small numbers of healthy adults designed to document a drug's safety and provide information about the effect of the drug on humans and any side effects associated with increasing doses of the drug. 21 CFR 312.21(a).

Then human testing on larger numbers proceeds, assuming nothing untoward has happened in the first part. This involves 200-300 people afflicted with a condition or disease, who are then treated with the drug. The results are evaluated to discover the effectiveness of the drug for particular indication in patients with diseases or conditions; then, to determine any side effects and problems associated with the taking of the drug in people with the target disease or condition. 21 CFR 312.21(b).

Finally, larger scale trials ensue, often involving thousands of patients with a specific target condition or disease. When this testing done by researchers paid by the drug companies is completed, the NDA is submitted to the FDA. 21 CFR 312.21(c); 21 CFR 314.50; 21 USC 335(b)(1).

C. The Pressures Faced By The FDA, And Their Effect On The Process

Throughout this seemingly involved process, the FDA has been shown to be not totally effective and, in some cases, totally ineffective, as to approval of new drugs. Many commentators, both in and out of the FDA—have commented on the pressures on the FDA at all stages of the drug approval process—pre-application, application judging itself and post-approval. For instance, the Bangor Daily News editorialized that the FDA's rush to approve a new diet drug to replace Fen-Phen—over the objections of its own staff—demonstrates the extreme pressure it is under to shed its alleged anti-business label and prevent any further attempts by Congress to abolish it. Bangor Daily News, Nov 29, 1997 (Appendix at 90b). On November 16, 1997, the Atlanta Journal, in an in-depth piece on the FDA process, stated that "squeezed between the vise-like jaws of public demand for fast approval of the latest wonder drugs, and Congressional pressures to reduce red tape, the FDA's review process is cursory at best, and little more than a rubber stamp at worst." (Appendix at 92b).

First, the FDA does no testing. Instead, the FDA relies on manufacturer-sponsored studies and is inclined to approve drugs despite marginal deficiencies in testing methods.

The previously cited Atlanta Journal article sheds some interesting light on the initial stage of the process—where drug companies generate the studies necessary to obtain approval for new drugs designed to alleviate or cure certain conditions. As recently as a decade ago, drug studies were usually conducted on college campuses, by ethical professors associated with a university hospital, and funded by one federal agency or another. However, multiple budget cuts have neutered federal research. To fill this void, drug companies have moved in, and are funneling money to private companies that are "quicker" and "more responsive" to the needs of the drug companies than the academic types. These days, most clinical trials are conducted off-campus by private researchers who can earn up to $20,000 for each patient subject they recruit and test. In 1990, there were about 5,000 researchers; in 1996, there were more than 33,000. **The FDA only has 38 people to oversee all**

clinical research work. The FDA looks in on less than 1% of clinical trials while they are being conducted. The only other oversight over private research companies is national for-profit institutional review boards, which are paid for their review by the drug companies being reviewed. (Id).

The Atlanta Journal constitution article reports on researchers manipulating data. A training manager for a Boston-based contract research organization, found a researcher forging test data, but did not do anything about it because the pharmaceutical company sponsoring the test didn't want to jeopardize the study. Similarly, a consultant in Decatur discovered unqualified patients were being enrolled in a cancer study, yet the drug company overseeing the study did nothing, because the doctor was an important researcher. Instead, the consultant, who was a monitor on the study, was removed from her position of over-sight. (Id).

The FDA's effectiveness in evaluating drug studies is also limited by its inability to attract and keep high caliber scientists and researchers, and, some allege, its questionable management. The limited testing done when the FDA has supervision over a new drug is usually insufficient to identify the hazards of a new drug. Paul J. Quirk, "Food & Drug Administration," in The Politics of Regulation at 191, 203-07 (1980). Indeed, one commentator, Teresa Schwartz, lists 11 instances in which products which were suspected of being dangerous were nonetheless either licensed or continued on the market by the FDA. Schwartz, "Punitive Damages and Regulated Products," 42 Am U L Rev 1335 (Summer 1993) (Appendix at 97b).

The pressures placed on the FDA to approve Redux were aggressive. Drug companies had direct contact with one or more members of the committee voting on whether or not Redux should be approved. Somehow, over the 45 days between the first and second votes, something happened to reverse the original negative decision.

The Raleigh News & Observer reports that the FDA must balance between protecting the public from inadequately tested medicines and making helpful new drugs available as soon as possible to those whose lives may depend on them. This pressures the FDA to reduce the time it takes for new drugs to reach the public. The current time frame for approval is 12 months—which precludes any significant research on the long-term effects of the drugs. In 1997, Congress passed a bill, S-830, reforming the FDA, which makes the approval process even shorter by requiring only one clinical trial which proves safety and efficacy. Raleigh News & Observer, Sept 22, 1997 (Appendix at 124b).

Thomas J. Moore, senior fellow of health policy at George Washington University Medical Center, wrote an editorial published in the Los Angeles Times, 4-5-98. In it, he states that the problem begins at the FDA, with the priorities imposed by limited budget and congressional mandates. For years, the chief complaint was that the FDA was too slow to approve new drugs. The FDA therefore was given additional funds collected from drug companies. The FDA then began responding more quickly in approving new drugs. Thus, a structural conflict of interest was created. As of 1997, the FDA approved new drugs as fast as, or faster than, European countries. Moore, "Prescription Drugs: Danger Within the Cure," LA Times, April 5, 1998 at M2 (Appendix at 126b).

After the FDA approves a drug, its monitoring of the drug continues, although in a much weakened way. The FDA acknowledged, through acting FDA Commissioner Michael Friedman, M.D., that there was a need for the agency to demonstrate the value of an effective post-marketing surveillance program. Also before Congress, Georgetown Dept. of Pharmacology Chairman Raymond Woosley suggested that the FDA's ability to conduct post-marketing research of products is hindered by reductions in its funding. New drugs simply being on the market carry an overhead that has to be addressed. He suggested that therapeutic research centers be developed to address the issue of more effective post-monitoring activity (FDA Pink Sheet, Nov. 24, 1997,

Appendix at 129b). Currently, the FDA's Medical Watch Program, the only program monitoring the continued efficacy of drugs approved onto the market by the FDA, gets by with a staff of four and a budget of $140,000. This constitutes less than one day's sales of Redux and Pondimin in 1998 (Wall Street Journal, Monday, Sept 29, 1997, Appendix at 133b). Furthermore, the FDA's Medical Watch Program relies on physicians voluntarily reporting side effects, and then on a handful of FDA employees spotting dangerous trends which may be developing. The FDA Drug Evaluation Director, Dr. Janet Woodcock, acknowledges that she is really unhappy about the internal system used to monitor continuing safety and efficacy of drugs after approval onto the market (Arizona Republic, Sept 21, 1997, Appendix at 135b).

D. Drug Companies' Response To FDA Problems

A number of states have statutes similar to Michigan's prior MCL 600.2946. They allow the defendant to submit evidence of statutory compliance to a jury, or establish a rebuttable presumption of safety given the statutory compliance. See, *e.g.*, Ark Code Ann 16-116-105(a) (1987); Colo Rev Stat 13-21-403(1)(a) and (b); Kan Stat Ann 60-3304(a); Ky Rev Stat Ann 411.310(2); NH Rev Stat Ann 507-D:4 (1983); Tenn Code Ann 29-28-104; Utah Code Ann 78-15-6(3); Wash Rev Code Ann 7.72.050(1).

A 1995 report on the Subcommittee of Pharmaceutical and Medical Devices, of the ABA Section on Products Liability Litigation, titled **"State by State Survey of the Effect of Compliance or Noncompliance with Federal Regulatory Standards in Pharmaceutical Product Liability Litigation"** shows that no state other than Michigan recognizes compliance with FDA regulations sufficient to confer immunity on a drug manufacturer so as to leave an injured patient without a remedy (Appendix at 138b).

Only Michigan has adopted a law that confers immunity on defendant manufacturers of a drug approved by the FDA. Although some aggressive legal scholars have recommended a regulatory compliance defense; see, *e.g.*, Green, "Statutory Compliance and Tort Liability: Examining the Strongest Case," 30 U Mich J L Ref 461 (1997); Jackson, "Pharmaceutical Product Liability May Be Hazardous to Your Health: A No Fault Alternative to Concurrent Regulation," 42 Am U L Rev 199 (1992); Ausness, "The Case for a 'Strong' Regulatory Compliance Defense," 55 Md L Rev 1210 (1996); none has ever advocated adoption of the drug manufacturer immunity that Michigan provides. Indeed, Professor Michael Green sums up what he deems "an important qualification on any FDA compliance defense" as follows:

> Preliminarily, and I believe uncontroversially, we should recognize that any defense based on FDA regulation would have to be structured as a compliance with FDA regulatory standards rather than as a defense based on FDA approval of the drug in question. The reason is quite simple but based on a fact that is not well known: The FDA's approval of a drug, which includes a determination of the appropriate labeling (i.e., warnings) **is wholly dependent on testing performed and reported by the sponsoring manufacturer**. The FDA conducts none of the testing to demonstrate that a proposed new drug is safe and effective required by the 1962 Kefauver-Harris amendments to the Food, Drug & Cosmetics Act for approval of new drugs by the FDA. The FDA does review the results of the tests performed by the manufacturer and submitted as part of its NDA; sometimes the FDA will review additional information or tests. In the end, it is the FDA that makes the judgment of whether a drug is safe and efficacious. Any conclusion that the FDA's approval represents a considered assessment that an approved drug's therapeutic benefits outweigh its risks, however, is unwarranted without manufacturer investigation that complies with FDA requirements for adequate and well-controlled studies of the new drug, accurate reporting of the results of those tests, and truthful responses to the inquiries by the FDA.
>
> Green, supra at 481. (Emphasis provided).

It has further been noted by many commentators that the FDA does not have sufficient resources or expertise to act independently, and may therefore lack information about product-related risks and safety technology. Schwartz, "The Role of Federal Safety Regulations in

Product Liability Actions," 41 Vand L Rev 1121, 1147 (1988). Government safety standards are also influenced by the degree of power exercised by the regulated industries and their political supporters in the legislative and executive branches over the agency itself. Johnson, "Products Liability Reform: A Hazard to Consumers," 56 NC L Rev 677, 687 (1978); Rose Ackerman, Comment, "Progressive Law & Economics—and the New Administrative Law," 98 Yale LJ 341, 363 (1988). Indeed, Johnson, in her article states flatly: "Manufacturers have enormous power to influence the formation of government standards, with the result that the standards are frequently political compromises at best."

Michigan Fen-Phen Litigation History

Against the backdrop of the new product liability legislative amendments in Michigan, and the development and inadequate testing and regulation of Fen-Phen and Redux, insofar as the complications these Plaintiffs complain of is concerned, comes the class action case of Tamara Taylor and Lee Ann Rintz. These class representatives represent a predicted 7,000-8,000 Michigan citizens injured by Fen-Phen and/or Redux. Many of these 7,000-8,000 citizens, without product liability recourse, will become tax burdens, with uninvolved Michigan taxpayers paying the tab for out-of-state drug manufacturers.

Tamara Taylor was treated with Fen-Phen from August 1995 to August 1997. Lee Anne Rintz was treated with Fen-Phen from March 1996 to March 1997. Both Taylor and Rintz developed primary pulmonary hypertension and other cardiovascular conditions. The effect of enforcing MCLA 600.2946(5) against these Plaintiffs will result in their and the class' failure to obtain just compensation from the defendant drug companies, including Appellant American Home Products (AHP), which has otherwise settled its cases nationally.

MICHIGAN'S UNIQUE FDA IMMUNITY STATUTE IS UNCONSTITUTIONAL BECAUSE IT IMPROPERLY DELEGATES TO THE FDA, A FEDERAL AGENCY IN THE EXECUTIVE BRANCH, THE MICHIGAN CONSTITUTION'S EXCLUSIVE GRANT OF LEGISLATIVE POWER TO DETERMINE AND DEFINE WHAT CONSTITUTES A CAUSE OF ACTION.

A. The Michigan Setting

The Michigan Constitution vests exclusive authority in the Supreme Court to establish the rules of practice and procedures for the court. This authority is found in the separation of powers provision of the Michigan State Constitution, as well as the article establishing the powers of the legislature and of the judiciary.

> The powers of government are divided into three branches: legislative, executive and judicial. No person exercising powers of one branch shall exercise powers properly belonging to another branch except as expressly provided in this constitution. 1963 Const, art 3, §2. . . . The legislative power of the State of Michigan is vested in a Senate and a House of Representatives. 1963 Const, art 4, §1. . . The judicial power of the state is vested exclusively in one court of justice. 1963 Const, art 6, §1. . . .

In light of the clear separation of powers established by the Constitution as well as the legislature's exclusive authority to define causes of action, Michigan courts have consistently held that legislation that impinges upon that area of authority granted exclusively to the legislature is unconstitutional. This line of constitutional authority flows from the cases governing the separation of powers.

Under the same constitutional provisions, and analysis, a governmental branch cannot delegate its functions to private citizens, or to non-state governmental authorities. Coffman v State Board of Examiners of Optometry, 331 Mich 582; 50 NW2d 322 (1951); In re Hawkins, 244 Mich 681; 222 NW 108 (1928); Knoke v Michelin Chemical Corp, 188 Mich App 456; 470 NW2d 420 (1991). The Michigan products statute, which grants immunity to drug manufacturers, improperly

delegates to the FDA the power to regulate who has access to the courts, and the authority to determine which drugs will be subject to product liability lawsuits. This is an unconstitutional delegation of legislative power to the FDA.

The lead case is Coffman, supra. In Coffman, the legislature prescribed rules to be followed by the State Board of Medical Examiners in Optometry in qualifying applicants for licenses. Plaintiff was declared ineligible to apply for licensing and challenged the statute, as well as rules promulgated by the Optometry Board. The statute stated in part, that any applicant was required "to have graduated from an optometric school or college rated as Class A or B by the International Association of Boards of Examiners in Optometry. . . ." The Michigan Supreme Court adopted an Attorney General opinion declaring this provision void, stating:

> The legislative power of this state is vested in the legislature and in the people by Const 1908, Art V. The legislature is prohibited by the Constitution from delegating legislative powers **to non-Michigan governmental agencies**—or to private individuals or associations. . . .
>
> Coffman, supra, at 587-88.

The principle that a branch of government cannot lawfully delegate to non-Michigan governmental agencies the authority vested in it by the Constitution is directly applicable to MCLA 600.2946(5). Thus, in Knoke, the issue was whether a trial court could dismiss a party's actions solely on the grounds that mediation panelists had found the action to be frivolous, and plaintiff had thereafter failed to file a bond. Plaintiff argued that this was an unconstitutional delegation to the Mediation Tribunal of authority to make final judicial decisions. The Court of Appeals upheld that position, ruling that plaintiff was entitled to a *de novo* hearing before the trial court. The trial court could not constitutionally delegate its dismissal powers to the mediation tribunal. 188 Mich App at 459-460.

Yet the Michigan legislature has delegated to the FDA, in MCLA 600.2946(5), the same power which was sought to be delegated to the Mediation Tribunal in Knoke. This is wrong. As

shown in Section II(c), at present, the FDA is ill equipped to handle the individualized balancing problems which are part of a drug product liability lawsuit. Equally important, depending upon the political tides of the moment, the FDA could be shorn of all of its investigative power, or reconstituted into something other than it is today. Yet the legislative mandate would continue on. Neither Michigan's legislature, or its courts, are empowered to delegate to the FDA the decision whether or not a cause of action is to be allowed. Allowing Michigan's Product Liability Act to stand constitutes an unconstitutional delegation of such power.

Finally, when the FDA does take after-market action, such is deemed irrelevant by the Michigan Statute. So the delegation to the FDA is not one to an agency which, in the scope of its business, is given free rein to perform its specialized function; it is to one part of the process, at the expense of the other parts. The Michigan legislature, in essence, has "amended" the FDA function to that of approval only. This is constitutionally impermissible.

Contrary to the arguments of Defendants, the standard of care is delegated to a federal agency. The statute allows the FDA to set the standard of care as relates to the safe manufacture of drugs. The FDA finding that Fen-Phen and Redux were safe and efficacious has now been withdrawn, yet Michigan consumers are bound by the original, now erroneous, finding of safety and efficacy of the FDA, by operation of 2946(5).

B. Unconstitutional Delegation of Power: An Overview

It is one of the oldest, and most cherished, principles of the American form of government that tyranny is prevented, and the republican form of government is enhanced, by a separation of governing powers among various bodies. Justice Houston, in a dissent in a recent Alabama Supreme Court case, Ex parte Legal Environmental Assistance Foundation, Inc, ___ So 2d ___; 2002 Westlaw 319224 (March 1, 2002), sets forth the traditional view:

> Under this principle, Congress and the state legislatures cannot delegate their lawmaking power, because that power ultimately does not belong to them; thus it is not theirs to delegate. These legislative bodies derive their power to pass laws from the people's consent to submit to the legislature's promulgation of those laws. "Governments . . . derive their just powers from the consent of the governed. . ." Declaration of Independence, para. 2 (U.S. 1976).
>
> Through the United States Constitution and their state constitutions, the people have granted to the three branches of government certain limited powers, with the understanding that those branches are in some measure controlled by the people. For the legislature to delegate its lawmaking powers to unelected bodies such as administrative agencies is to distort, and perhaps even destroy, that understanding that exists between the government and the people; it is as unacceptable as the judiciary's usurping the legislature's lawmaking power. Indeed, having an unelected, unaccountable body making and enforcing the laws is the very definition of tyranny.
>
> Id, Slip Op, at 6.

C. Federal To Federal Delegation

Judge Houston's view—that delegation was entirely unacceptable, as a violation of the compact between the government and the people—held sway throughout the early part of our nation's history, into the 20th Century, when the United States Supreme Court involved itself with the delegation of legislative powers to a non-legislative actor or body. Perhaps the high water mark of this view was the early New Deal cases, Panama Refining Co v Ryan, 293 US 388; 55 S Ct 241; 79 L Ed 446 (1935), and Schechter Poultry Corp v United States, 295 US 495; 55 S Ct 837; 79 L Ed 1570 (1935). In the decades following those opinions, although the Panama Refining and Schecter Poultry holdings were never overruled, the Supreme Court has not seen fit to extend the principles set forth therein. Justice Marshall perhaps summed it up best when he stated that "the notion that the Constitution narrowly confines the power of Congress to delegate authority to administrative agencies, which was briefly in vogue in the 1930's, has been virtually abandoned by the court for all

practical purposes." Fed'l Power Comm'n v New England Power Co, 415 US 345, 352-53; 94 S Ct 1151, 1156; 39 L Ed 2d 383 (1974).

In very recent years, one commentator, Prof. Bressman, has identified a "new delegation doctrine" as typified by such cases as AT&T Corp v Iowa Utilities Bd, 119 S Ct 721 (1999), and American Trucking Ass'n v EPA, 175 F3d 1027, modified in part and rehearing *en banc* denied, 195 F3d 4 (DC Cir 1999). See "Schecter Poultry at the Millenium: A Delegation Doctrine for the Administrative State," 109 Yale LJ 1399 (2000). Delegations to private agencies continue to be struck down pursuant to the delegation doctrine. See, *e.g.*, Mich Pork Producers Ass'n v Campaign for Family Farms, 174 F Supp 2d 637, 645-46 (WD Mich 2001). However, Prof. Bressman explains, citing Justice Scalia in Mistretta v United States, 488 US 361, 415-16 (1989), that only recently has legislation delegating legislative power to administrative governmental agencies come back under scrutiny:

> Justice Scalia has offered an explanation for the court's reluctance in this area. Although the court has not renounced the importance of the non-delegation principle in "our constitutional system," it has acknowledged that centrality of delegation in our modern government. Moreover, the court has recognized that once some delegation is permitted, "the debate over unconstitutional delegation becomes a debate not over a point of principle but over a question of degree." Furthermore, "the limits of delegation must be fixed according to common sense and the inherent necessities of [government]." Because this determination requires considerations of factors "both multifarious and (in the non-partisan sense) highly political," the court has "almost never felt qualified to second guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law."
>
> 109 Yale LJ at 1405-06 (footnotes omitted).

Thus, the current state of the non-delegation doctrine at the federal level is in flux. It is expanded and compressed to meet the needs of a given situation, while paying proper deference to the legislature and its need to vest in those bodies which are better qualified and more directly on line the duty of setting standards, enforcing those standards and keeping the machinery running in general.

This Court, faced with a question of first impression, not only in Michigan's experience, but in the experience of the nation, can take these principles to heart. Furthermore, the non-delegation doctrine is buttressed by other important policy considerations when it is addressed on the state constitutional level, especially in the context of a state delegation to a federal administrative agency—which gives conclusive effect to one decision of that federal agency, and refuses to recognize a second, more recent decision. These will be examined in the coming sections.

D. State To State Delegation

Professor DaBow notes the difference between the federal delegation doctrine, and that observed at the state level:

> But how important is separation of powers to American government in 2001? The concept has taken quite a beating in the federal government over the last century or so. The rise of federal administrative government involving much mixing of governmental powers within administrative agencies, and very significant delegations of legislative power to these agencies. The result has been called "a bloodless constitutional revolution" by one commentator, and "Madison's nightmare" by another.
>
> The good news is that the separation of powers is a stronger concept in state constitutional law. Most state governments have historically been rooted in a strong preference for a strict separation of powers among the executive, legislative, and judicial departments.
>
> DaBow, "The State Tobacco Litigation and the Separation of Powers in State Governments: Repairing the Damage," 31 Seaton Hall L Rev 563, 589; citing Crewman, "Between Authority and Liberty: State Constitution Making in Revolutionary America," 109-30 (1997); Rossi, "Institutional Design and the Lingering Legacy of Anti-Federalist Separation of Powers Ideals in the State," 52 Vand L Rev 1167, 1187-89 (1999).

This was echoed in recent case notes involving Texas—Brown, "Legislative Branch—Of Water and Weevils, The Texas Supreme Court Further Restricts the State Legislature's Power to Delegate to Private Entities, FM Properties v City of Austin, 22 SW3d 868 (Tex 2000)," 32

Rutgers LJ 1482 (2001); "New York State Constitutional Decisions: 1997 Compilation, Separation of Powers," 14 Touro L Rev 1271 (Spring 1998) (discussing Dorst v Petaki, 228 A2d 4, 654 NYS2d 198 (1997)). Both of these scholarly discussions of case law recognize the fact that state judiciaries, working either within an explicit state constitution, or within a traditional state framework recognizing the need for stricter separation of powers than at the federal level, are far more likely to strike down legislation which improperly delegates such powers. See, *e.g.*, Advisory Opinion in re Separation of Powers, 295 SE2d 589 (NC 1982); Levine v Whalen, 39 NY2d 510; 349 NE2d 820; 348 NYS2d 721 (1976).

In states with strong policies against delegation, a common test is the "sufficient standards" test. As set forth in Healthscript, Inc v State, 770 NE2d 810 (Ind 2002), "the legislature may constitutionally delegate rulemaking powers to an administrative agency if that delegation is accompanied by sufficient standards to guide the agency in the exercise of its statutory authority." Id at 814. To similar effect is Edgewood Independent School Dist v Meno, 917 SW2d 717, 740 (Tex App 1995), which held that delegations to public entities were permissible so long as the legislature provided "reasonable standards to guide the entity as to which powers are delegated."

This type of case—where a legislature, setting reasonable standards and guidelines, delegates some of its authority to an inferior, in state administrative body—constitutes the overwhelming majority of the material and cases relied upon by the Defendants in their briefs. Falling into this category are the cited cases of Fullmer v Gensen, 379 NW2d 736 (Neb 1986); Johnson v Pearce, 313 So 2d 812 (La 1975); Lee v Delmont, 36 NW2d 530 (Minn 1949); Montoya v O'Toole, 94 NM 303; 610 P2d 190 (1980); and all of the criminal cases cited by Defendants in their briefs.

The situation facing this Court is far different. None of the cases cited gives support to the delegation of an essential legislative power—the power to define what constitutes a cause of action—to a federal agency outside of the legislature's control to influence in any way. Far from

submitting to the agency guidelines and standards, under 600.2946(a)(5), the legislature defers to the decision of the FDA to declare a drug marketable, even in the face of a later FDA decision to withdraw the drug as no longer safe to be marketed. This constitutes an out and out abdication of the legislative power to a federal agency, which is completely outside of the legislatures control, and whose entire system of dealing with the problem the legislature has delegated to it is not incorporated into the legislative scheme. This is entirely unheard of; this calls for delegation of powers analysis applied in an unprecedented setting.

The best response this Court could give would be to uphold the outright prohibition set forth by the Coffman court, as to delegation of fundamental legislative power to outside federal agencies. The next best, more flexible approach, would be to prohibit such delegation when, at the very least, the entirety of the federal scheme is not incorporated within the legislative delegation of power. Either such approach would be in keeping with this State's traditional reservation of power to the legislature, even where the legislature attempts to unconstitutionally divest itself of such power.

E. Michigan's Unique State To Federal Delegation

Defendants are unable to cite a persuasive case where fundamental state powers, traditionally reserved for the legislature, are delegated to an outside federal agency—in whole or in part. The unwisdom of doing such spreads across two conceptual boundaries—federalism, state v. federal; and separation of powers, legislative v. executive/administrative. Essentially, the legislature is deferring to the FDA in an area where the FDA does not defer to itself. The legislature is ensconcing a single FDA decision as dispositive, in an area where FDA itself does not ensconce such a decision. Finally, the legislature passes to the FDA a power which the FDA does not arrogate to itself, and has never been ascribed to the FDA, even in the federal cases, or in out-of-state cases, regarding delegation of power or preemption of administrative authority.

A concern for federalism underlies the Coffman prohibition against state delegation to federal agencies. As pointed out by Justice Briar in a dissent in United States v Morrison, 529 US 598, 655; 120 S Ct 1740; 146 L Ed 2d 658 (2000), the purpose of federalism and the purpose of the doctrine of enumerated powers are to protect individual liberty. "No one denies the importance of the Constitution's federalist principles. Its state/federal division of authority protects liberty—both by restricting the burdens that government can impose from a distance and by facilitating citizen participation in government that is closer to home." Although definitions of federalism in the state/federal context are fluid, and the subject of considerable academic dispute—compare Barnett, "The Original Meaning of the Commerce Clause," 68 U Chi L Rev 101 (2001) with Pushaw & Nelson, "A Critique of the Narrow Interpretation of the Commerce Clause," 96 NW U L Rev 695 (2002)—these debates occur largely in the context of whether Congress is accorded the right, under the federal Constitution, to arrogate to itself powers that tradition, and the Eleventh Amendment, have seemingly reserved for the states. See, e.g., Rotunda, "The Eleventh Amendment, Garrett, and Protection for Civil Rights," 53 Ala L Rev 1183 (2002). From a state point of view, as Michigan, there are compelling reasons to adopt a strict prohibition against the delegation to the ravenous federal maw beyond that which it is already arrogating unto itself. However well intended, the enactment of 600.2946(5) is such a breach of fundamental federalist concerns.

In short, what the legislature has sought to do may well be an acceptable goal. The legislature has many ways in which it can ease the burden upon drug manufacturers, including the granting of out-and-out immunity to them, unconditioned upon anything. What it may not do is transfer state power to the federal agency to determine when a Michigan citizen can bring a lawsuit. Even under the most flexible of approaches, to allow delegation to an agency, without legislative guidelines or standards, in an area where the agency itself does not determine "once and for all" the safety and efficacy of a drug under its jurisdiction, is the ultimately unconstitutional unwisdom.

Furthermore, the Court of Appeals Opinion makes it clear that Plaintiffs did not prevail in this matter merely by pointing out that the legislature acted unwisely. Defendants' citations to other cases where federal findings are incorporated into state statutes do not rise to the magnitude of what has occurred here. This matter thus falls under the Coffman standard rather than under that of the cases cited by the defendants. Thus, again using the interest rate analogy, SmithKline Beecham's argument that this statute should be held constitutional, for the same reasons that state statutes adopting the federal interest rate for interest on judgments are valid, is wrong for two reasons. First, the interest rate to be charged is a mere procedural step, and does not affect the substantive rights of the parties; it simply sets the amount. Second, and more importantly, when interest rates change, the state interest rate also changes. In this case, when the FDA's recommendation changes, however, the recommendation does not change. It does not pass through, as it would were it a mere reference statute. Instead, this statute sets forth an immunity for drug manufacturers, which immunity is absolutely dependent on past actions of a federal agency outside of the control of the Michigan legislature and outside of Michigan court. Even where the federal agency later changes its stance, the immunity remains. Under Coffman and Knoke, this is an improper and unconstitutional delegation.

This part of the Court of Appeals Opinion bears repeating—it deals with the argument made by Defendants, and the court's response to it:

> Defendants contend that pursuant to the doctrine of "independent significance", courts routinely uphold against similar constitutional challenge the assimilation into statutory law of standards and determinations of public and private organizations. Defendants argue that the controlling factor determining constitutionality is whether the assimilated standards were adopted specifically for the purpose of the legislation at issue; if not, no delegation occurred. Defendants assert that the FDA determinations have legal consequences with independent, nationwide significance. They maintain that by adopting these external standards as its own, in the exercise of its lawmaking power, the legislature has merely established the manner in which these legal consequences are to pertain to Michigan product liability law.

> The short and simple response to this almost convincing argument is found in the test previously discussed in connection with reference statutes. See Dearborn, supra; Radecki, supra. Assimilation of standards adopted for a purpose separate from the incorporating legislation, and having independent significance, presents no problem if the standards are established and essentially unchanging. Where, however, as here with the FDA efficacy determinations, it is known at the outset that the relevant feature will be in constant flux, a fatal problem does present itself under the constitutional non-delegation doctrine as developed and applied in Michigan.

This Opinion is legally correct. The legislature retains the powers to redefine what constitutes a product liability cause of action as to prescription drugs in Michigan; it simply cannot do so in an unconstitutional fashion. The Court of Appeals citations to Dearborn Independent, Inc v City of Dearborn, 331 Mich 447; 49 NW2d 370 (1951), and Radecki v Director of Bureau of Workers' Disability Compensation, 208 Mich App 19, 23; 526 NW2d 611 (1994), should be accepted as the controlling law in this area.

This is a narrow area, and a specific ground of unconstitutionality, unrelated to most of the actions taken by the legislature in its 1994 and 1996 tort reform legislation. This will not lead to great destabilization, or massive nullification of statutes enacted by the legislature. Indeed, the legislature remains free to reenact the instant statute, without the fatal constitutional defect. However, with the constitutional defect as it now exists, the Court of Appeals decision must stand, and the Fen-Phen class appellees ask that this Court deny Defendants' Applications for Leave to Appeal.

CONCLUSION

A statute being declared unconstitutional is not a frequent event. Even more infrequent is an occasion when a statute is declared unconstitutional by a lower appellate court, without the State Supreme Court granting leave to consider the issue. However, such a course of action is available to this Court, and would be the preferable course of conduct in this case. The Court

of Appeals reached the right conclusion for the right reasons. This Court retains the discretion to allow the Court of Appeals decision to remain the binding statement on this area of law by simply denying Defendants' applications for leave to appeal. If this Court does accept Defendants' applications because of the importance of the jurisprudential issue involved, it should do so in order to affirm the Court of Appeals Opinion.

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September 30, 2002.

Mary B Bergmann
Notary Public, Wayne County, Michigan
My commission expires: 03/17/04